closed if insufficient or incomplete information has been submitted to enable the Commission to evaluate the merits of the exemption request.

§1702.5 Failure to supply adverse information.

Failure to obtain and provide the Commission with all reasonably available information that the petitioner knows is unfavorable or could reasonably expect to be unfavorable to the petition shall result in the denial of the petition.

§1702.6 Trade secrets and other confidential information.

Where a petition contains material that the petitioner believes should be exempt from public disclosure under the Freedom of Information Act, 5 U.S.C. 552, the petitioner shall comply with the requirements of 16 CFR part 1015, the Commission's regulation under the Freedom of Information Act concerning requests for treatment as exempt material. The Commission shall act upon any request for treatment as exempt material in accordance with the provisions of 16 CFR part 1015.

§1702.7 Justification for the exemption.

The justification for the exemption, required under §1702.3, shall explain the reason for the exemption based on one or more of the following grounds:

(a) If the justification is based on a lack of need for special packaging to protect young children from serious injury or illness from the substance, the justification shall state how the lack of toxicity and lack of adverse human experience for the substance clearly supports granting the exemption.

(b) If the exemption is requested because special packaging is not technologically feasible, practicable, or appropriate for the substance, the justification shall explain why.

(c) If the exemption is requested because special packaging is incompatible with the particular substance, the justification shall explain why.

§1702.8 Human experience data.

Human experience data constitutes the primary criterion used by the Commission in evaluating petitions for exemptions. Petitions shall therefore include a compilation of all reasonably available reports pertaining to human use of the particular substance, including the product brand as well as generic equivalents and involving adverse reports of personal injury, illness, and significant allergenicity. Such information in children is of particular importance in evaluating exemption requests. However, similar data in adults shall also be submitted if available. Human experience data may be obtained from such sources as:

(a) Reports from Poison Control Centers,

(b) Reports of adverse reactions relative to the product that have been submitted to the company by physicians, hospitals, consumers, and other sources,

(c) Extensive searches of the medical, pharmacological, and toxicological literature, and

(d) For drugs, where the human experience data submitted is based on data required by FDA to be compiled for an Investigational Exemption for a New Drug (IND), 21 CFR part 312, or a New Drug Application (NDA), 21 CFR part 314, a summary of the relevant data should be provided. The entire NDA and IND material need not be submitted.

§1702.9 Relevant experimental data.

Experimental data are generated in both animals and humans in controlled situations in order to evaluate the biological effects of a substance. Certain toxicological effects cannot generally be evaluated in human beings. This is especially true of those substances which are not normally intended to be used in or on the human body or animal body. Therefore, the Commission considers experimental data obtained in animal studies to be an important supplement to such data as may exist from any experimental studies conducted in humans. The minimum toxicological evaluation necessary for a particular household substance is proportional to the expected exposure of man to that substance. Household substances which are not expected, in normal use, to contact man are subject to